MAR 2 0 2013

510(k) Summary

The purpose of this Traditional 510(K) is to gain clearance for the CPS Aim™ Universal slittable inner catheter. The key design features of the CPS Aim™ Universal slittable inner catheter have only undergone a minimal change to increase the inner diameter of the catheter as compared to the predicate, CPS Aim® SL slittable inner catheter (K090613).

Submitter:	St. Jude Medical,CRMD
Address:	15900 Valley View Ct Sylmar, CA 91342
Phone:	818 493 2960
Fax:	818 493 3615
Contact Person:	Colleen Canan
Trade Name/Proprietary Name:	CPS Aim™ Universal slittable inner catheter
Common Name:	Percutaneous Catheter Model Numbers: DS2N026-59, DS2N027-59, DS2N028-59, DS2N026-65, DS2N027-65, DS2N028-65, DS2N029-65, DS2N030-65
Classification:	Class II, 21 CFR 870.1250
Legally marketed device to which your firm is claiming equivalence:	CPS Aim® SL slittable inner catheter (K090613)

Device Description:

The device description of the CPS Aim™ Universal slittable inner catheter is as follows.

The CPS Aim™ Universal slittable inner catheter (subselector/cannulator) is used to facilitate left heart lead delivery procedures. It is an introducer that is used to cannulate the coronary venous system and act as a conduit for contrast medium, implantable coronary leads, or other devices. The CPS Aim™ Universal slittable inner catheters will be available in the same working lengths, 59 and 65 cm as the predicate and will be available with the same number of curves as the predicate. The key design features of the CPS Aim™ Universal slittable inner catheters have only undergone a minimal change to increase the inner diameter of the catheter and the accessories have not changed. The key design features are listed below:

- Braid reinforced, varying durometer PEBAX shaft with molded proximal hub.
- Inner diameter of the catheter is PTFE lined
- Atraumatic distal soft tip.
- Embedded marker band on soft tip for fluoroscopic visibility.
- Outside surface of the catheter shaft is coated with a hydrophilic coating to provide lubricity during use.
- Hub of the catheter is fitted with a retention cap and an integrated valve that includes a sideport assembly with 3-way stopcock.
- The catheters are available in cannulator and sub-selector models.
- Accessories such as VBT used to assist the insertion of SJM Devices (leads, guidewires, inner catheters, etc)

The indication for use is as follows:

The St. Jude Medical CPS Aim™ Universal slittable inner catheter (subselector/cannulator) is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for delivery of contrast medium and St. Jude Medical devices (such as guidewires and implantable left heart leads). In addition the CPS Aim Universal slittable inner catheter (subselector/cannulator) can work with outer guide catheters as a system.

Technological Characteristics of the Device Compared to the Predicate Device:

The device has the same technological characteristics as the currently marketed CPS Aim® SL slittable inner catheter, with only minimal changes to the inner diameter, outer diameter, valve bypass tool, and design of shaft and hub to accommodate change in diameter of the catheter . Where differences exist between the subject device and the predicate devices performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the subject devices.

Non-clinical Test Summary:

Completion of all verification and validation activities demonstrated that the candidate devices meet their predetermined design and performance specifications and that the products are substantially equivalent to the predicate devices (**Appendix 1**).

Conclusion (Statement of Equivalence):

The results of the verification and validation tests and the risk analysis have demonstrated the CPS Aim™ Universal slittable inner catheter functions in accordance with product specifications. St. Jude Medical considers the CPS Aim™ Universal slittable inner catheter to be substantially equivalent to the legally marketed predicate device, the CPS Aim® SL slittable inner catheter cleared in 510(k) K090613.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

St. Jude Medical, CRMD
C/O Colleen Canan
15900 Valley View Ct.
Sylmar, CA 91342

Re: K130252
Trade/Device Name: CPS AIM™ Universal Slittable Inner Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: January 29, 2013
Received: February 1, 2013

Dear Ms. Canan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	K130252
Device Name	CPS Aim™ Universal slittable inner catheter
Indications for Use	The St. Jude Medical CPS Aim™ Universal slittable inner catheter (subselector/cannulator) is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for delivery of contrast medium and St. Jude Medical devices (such as guidewires and implantable left heart leads). In addition the CPS Aim Universal slittable inner catheter (subselector/cannulator) can work with outer guide catheters as a system

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_____ OR Over-The-Counter Use_____
(Per 21.CFR 801. 109)

Owen P. Faris -S
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